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(54) Title: DEVICE FOR CUSHIONING OF COMPRESSION SURFACES

(57) Abstract: According to the present invention, improved methods and apparatus are provided for providing cushioning and other ergonomic surfaces on devices requiring the patient or tissue to be compressed, such as radiography machines, fluoroscopy units, mammography units and the like. In particular a radiolucent pad element is provided for releasable attachment to at least one surface of a compression device to be used under x-ray, for example, during mammography. The pad element of the present invention can be disposable or constructed to be reusable and in some cases may be applied directly to the patient's breast. Furthermore, a cushioned compression paddle or x-ray plate is provided wherein said compression paddle or x-ray plate and said cushion can be separately or integrally formed.

DEVICE FOR CUSHIONING OF COMPRESSION SURFACES

BACKGROUND OF THE INVENTION

The present invention relates generally to medical apparatus and methods and more particularly to devices and methods for cushioning or padding the surface of compression plates applied to body parts for purposes of obtaining x-ray films, for example, mammography, or other scans of compressed tissue.

Currently, in the case of mammography, a patient's breast is placed under compression by opposing plates attached to a mammography machine. Once under compression an x-ray is taken to determine the presence or absence of suspect lesions in the breast tissue (e.g. calcifications, tumors). Approximately 25 million screening mammograms are performed yearly, which is estimated to be only a 50% compliance rate among potential patients, meaning that number would double if all potential patients complied with the recommended screening regime. One of the more common complaints from mammography patients is discomfort during compression of the breast. Most patients can only tolerate up to 10-11 compression units. The current legal limit for clinical mammography is 16-18 units. A device which would reduce discomfort could likely improve compliance for screening.

An important reason for compressing the breast during mammography is to provide a thinner cross section of tissue for the x-rays to pass through. When the breast is compressed, it provides optimal imaging of the tissue abnormalities with the lowest possible dose of x-ray radiation to the patient. Furthermore, during a mammogram, it is important for the x-ray plate to be free from radiopaque material, so that the diagnostic film, once processed, can give the physician the best possible picture of the tissue and any abnormalities.

Although patients may tolerate the pain during compression, there is a need for improved devices and techniques to provide better screening outcomes by enabling the use of higher compression force, and by providing increased patient comfort during mammograms thereby positively impacting patient compliance with mammographic screening and ultimately impacting early detection of cancer and improving patient survival.

Such improved devices must be radiolucent and made of a relatively homogeneous material to avoid striations or other variations on the resulting x-ray image, have a low profile to allow for correct positioning of the breast in the mammography machine, be easily cleaned or disposable for sanitary reasons, and provide structural support and tactile comfort to the patient (both soft to touch and providing a less harsh or "cold" surface). In addition, such improved devices will permit the use of higher compression forces to be applied to the breast during mammograms without the patient reaching her tolerance level for discomfort, resulting in a thinner tissue section, better image quality, and reduced x-ray dose to the patient.

It is an objective of the present invention to provide greater patient comfort thereby increasing screening compliance (e.g. patient willingness to have more regular mammograms by reducing discomfort of the procedure). Greater patient comfort also reduces the risk of patient movement (voluntary or involuntary). Motion artifact, caused by patient movement or slippage of the tissue, can result in loss of clarity of the mammographic image. It is a further objective of the present invention to allow for the use of an increased compressive force, for example, up to 16-18 compression units or more thereby providing for a thinner cross-section of breast tissue during the mammogram resulting in an enhanced ability to detect abnormalities in the mammographic image. These objectives are met by the design and use of the present invention.

DESCRIPTION OF THE BACKGROUND ART

Various patents have issued illustrating inventions in the field of mammography and comfort during x-ray imaging. For example, in the field of mammography, US Patent Nos. 3,963,933, 4,691,333, 4,943,986, 5,189,686, 5,553,111 and 5,398,272 describe various fixtures useful for breast compression. Further, patents have issued describing devices for increasing comfort during general x-ray procedures, such as US Patent No. 5,226,070 (radiolucent x-ray mat), US Patent No. 5,081,657 (buckey warmer for mammography machine), US Patent 5,541,972 (disposable padding device for use during mammography) and US Patent No. 5,185,776 (padded cover for x-ray cassette).

SUMMARY OF THE INVENTION

According to the present invention, improved methods and apparatus are provided for cushioning or providing other patient comfort surfaces on devices used for compressing the patient's tissue, such as radiography machines, fluoroscopy units, mammography units and the like. In particular a pad element is provided for releasable attachment to at least one surface of a compression device to be used under x-ray, or other imaging modality.

In a preferred embodiment of the present invention a pad assembly is provided consisting of a pad element, an adhesive layer and a release paper layer allowing for temporary attachment to the applied surface (either the mammography paddle, x-ray plate or directly to the patient's skin).

An alternative embodiment of the present invention includes a reusable cushioned paddle configured of a self-skinned foam to allow for easy cleaning between patients. This embodiment

may be replaceable after many uses or formed integrally wherein the padded surface and the compression paddle are assembled as one unit.

The present invention may also incorporate a dispensing unit for access to single pads for single use.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a typical mammography unit having a base and a pivoting x-ray unit attached thereto, the x-ray unit including a compression paddle and an x-ray plate.

FIGS. 2A-2B illustrate detailed construction of the x-ray plate and the compression paddle respectively.

FIGS. 3A-3C illustrate various configurations of compression paddles utilized during mammography in a standard mammography machine; the shape and size depending both on the patient's anatomy and the type of x-ray view desired by the physician.

FIGS. 4A-4B illustrate various attachments that can be placed on the x-ray plate to enhance the image, including devices for spot compression and magnification.

FIG. 5 illustrates a compression paddle and x-ray plate configured for use in a stereotactic biopsy procedure.

FIGS. 6A-6C illustrate the pad of the present invention having a padding layer, an adhesive layer and a release paper layer.

FIGS. 7A-7B illustrate the installation of the pad of the present invention on an x-ray plate.

FIG. 8 illustrates the installation of the pad of the present invention on a compression paddle.

FIG. 9 illustrates various pad configurations and geometries according to the present invention depending on the type of compression paddle or x-ray unit used in a given procedure.

FIG. 10A illustrates an alternative embodiment of the present invention, showing the use of a self-skinned foam fastened to a compression paddle intended for use on multiple patients.

FIGS. 10B-10C further illustrate an alternative embodiment of the present invention wherein the pad and compression paddle are integral as one unit.

FIG. 10D illustrates an alternative embodiment of the present invention, wherein the pad and x-ray plate are integral.

FIG. 11 illustrates a further feature of the present invention, namely a dispensing unit for storing and dispensing the disposable pads of the present invention to promote ease of use and efficiency.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A typical or standard mammography unit used to image the breast while under compression is shown in Fig. 1. This unit 10 includes a base 12 and a rotating x-ray source 11, comprising an x-ray source 13, a movable compression paddle 14 and an x-ray plate 15 that holds the film cassette (not shown) as well as serving as a compression surface against which the compression paddle 14 can compress tissue, e.g., a breast to be imaged. As depicted in Fig. 2A, typically the x-ray plate 15, in certain configurations known as a "bucky," is stationary and

includes an opening 16 into which an x-ray cassette 17 is placed prior to imaging. The x-ray plate has two patient contact surfaces, a front face 18, and a functional surface 19. The x-ray plate 15, may optionally include radiopaque markers 19A at the perimeter of the functional surface 19 to allow various marking schemes to be utilized during a procedure.

Fig. 2B illustrates a more detailed configuration of compression paddle 14, including a front patient contact surface 20 and a functional patient contact surface 21. Paddle 14 is typically constructed of a clear radiolucent plastic material and is designed to be removably attached by an interchange assembly 22, to the movable working arm of the mammography machine (not shown). These paddles are configured in various geometries as depicted in Figs. 3A-3C to accommodate various patient anatomies and specific needs of mammographers, such as coned compression paddles (3A), spot compression paddles (3B) and the axillary paddle shown as Fig. 3C, all configured to attach to the mammography unit through standard interchange assembly 22, as shown earlier.

Similarly, the x-ray cassette holder may be adapted by various ancillary modules such as the spot compression fitting 41 shown in Fig. 4A, and a magnification fitting 42 shown in Fig. 4B. The entire compression system (compression paddle and x-ray plate) can further be modified to accommodate a stereotactic biopsy procedure as illustrated in Fig. 5. In this configuration, compression paddle 14 is modified to include a window 51, allowing the clinician access to the breast, while still under compression, for purposes of placing a device to identify a specific location in the breast, or to perform a biopsy of tissue.

A preferred embodiment of a pad assembly constructed in accordance with the present invention is illustrated in Fig. 6A. The pad assembly 60 comprises a padding element 61, an

adhesive layer 62, and a release paper 63 to be removed from contact with the adhesive layer just prior to installation on the surface to be padded. Pad element 61 may be constructed of various materials having the following characteristics: produce no significant visual artifact on the mammogram (i.e. is radiolucent), be deformable under the forces applied during compression to provide comfort. Furthermore, the material should provide conformance to the tissue and the compression surface so as to reduce the propensity for the material to create air pockets or folds that may be of sufficient size to be visible on the x-ray image. Additionally, it may be desirable for the material to be absorptive to external fluids such as sweat.

Such materials may be an elastomer or gel, open (reticulated) or closed (non-reticulated) cell foam consisting of polyolefin, or, preferably, a polyurethane open cell foam because of its radiolucent characteristics and soft tactile feel. Of particular advantage is polyurethane foam having a density of 5-6 lbs./cu ft, with approximately 90 pores per inch. The padding material 61 may be a thickness of .050" to .500", preferably in the range of .200" and .250". If an adhesive layer is used, adhesive layer 62 may be one of a variety of currently available pressure sensitive adhesives such as acrylic or synthetic rubber based adhesives, to allow sufficient tackiness for secure attachment to the compression surface, while also allowing for easy removal (e.g. leaving no detectable residue of adhesive on the applied surface) and disposal. Alternatively, a non-adhesive gel may be used to secure the pad or another layer of material having a greater coefficient of friction against the applied surface. It is also anticipated by the scope of the present invention that the pad element may itself be textured such that it is sufficiently "tacky" to enable its use without an adhesive layer, i.e., by means of friction between the element and the tissue and the unit compression surface.

The pad element of Fig. 6A can be configured with adhesive on the entire surface of the pad, or at certain regions such as just along the border (see Fig. 6C). Fig. 6B depicts a "peel away" packet configuration to house the pad assembly; optionally, the peel away packet can serve as a stiffening element to aid installation of the pad by keeping it in a planar configuration to minimize the possibility of misapplying the pad (leading to inadvertent air pockets or folds in the material, etc.) and to aid in positioning the pad prior to adhering it to the applied surface.

Fig. 7A illustrates, in stepwise fashion, the installation of the pad assembly 60 of the present invention onto the film holder 15. The first step comprises opening the packing material housing the pad assembly 60 (S1), and thereafter removing any release paper 63 therefrom (S2). The pad assemblies can be packaged individually or in bulk. Installation on the patient contact surfaces of the x-ray plate 15 are shown in steps S3 and S4, S3 showing the placement of the pad element 61 on functional surface 19, and optionally extending to front face surface 18. The installed pad is depicted in Fig. 7A. Fig. 7B shows an alternative embodiment of pad element 61 installed onto an x-ray plate where the pad is configured to stretch over side face 23 of the x-ray plate, to provide added comfort for the patient. More particularly, the pad of this embodiment includes an adhesive layer which is preferably of a three part construction: a high tack, high peel permanent adhesive securing the adhesive layer to the pad element, a low tack, removable adhesive for securing the adhesive layer to the patient contact surface of the x-ray plate, and a stretchable carrier material between the two adhesives, such as polyethylene. A pad according to the present invention can also be formed of a similar construction using, e.g., polyester as a carrier material. Finally, the pad element may be removed and disposed of and the sequence repeated for the next patient. It may be desirable to score or otherwise provide a fold in the pad

element at a fixed point from the edge of the pad to accommodate folding the pad onto the front and/or side face of the applied surface.

A similar sequence of steps (S1 to S4) is illustrated in Fig. 8A showing the installation of pad assembly 60 of the present invention onto compression paddle 14. The pad assembly (PA) of Fig. 8B is configured such that portions of the pad extend to cover side surface 24 of the compression paddle, providing added comfort for the patient.

It should be noted that the pad of the present invention may be installed on the x-ray plate 15 and the compression paddle 14, or one and not the other, and further optionally on the front face and/or side face of either surface depending on the amount of additional cushioning desired. In experimentation with the present invention, increased comfort was noted in all of the various configurations as compared to unpadded compression surfaces.

An alternative technique for use of the pad is to attach it to the breast of the patient instead of on the mammography machine itself. In this technique (not shown) the release paper is removed and the adhesive side of the pad is placed directly on the breast in an area of tissue to be compressed prior to placing the breast into the mammography machine.

Typical geometries of the present invention are illustrated in Fig. 9, including pad elements for x-ray plate 15 (G1), pad elements with windows for stereotactic use (G2), spot compression paddles (G3), coned compression paddles (G4), and axillary paddles (G5).

It is noted that while these configurations reflect the geometries of various commercially available compression paddles and x-ray cassette holders, the present invention may be manufactured in a wide array of sizes and shapes. The present invention includes pad

assemblies, where the pad elements are modular (e.g. using more than one pad to cover a desired surface), or cut to fit the desired surface (oversized with an overlay pattern to guide the operator in cutting the pad to fit).

An alternative embodiment of the present invention is illustrated in Figs. 10A-10C. Fig. 10A shows a modular configuration of the present invention wherein the pad assembly is constructed from a self-skinned foam (PA), i.e., foam having an impermeable membrane covering, such as a vinyl, deployed over a frame (not shown) and fastened to a compression paddle by suction cups, magnets rivets or adhesive (AD) on the non-functional surface of the compression paddle or x-ray plate. The self-skinned configuration of the pad assembly allows for washing or disinfecting and can therefore be applied for multiple patients.

Fig. 10B illustrates a pad assembly (PA) attached to the paddle on the nonfunctional surface by snaps or rivets 110. Fig. 10C further illustrates an alternative embodiment of the present invention wherein the pad 120 and compression paddle 121 are a single integral unit. Fig. 10D illustrates an alternative embodiment of the present invention wherein pad 122 and x-ray plate 123 are a single integral unit.

Fig. 11 illustrates a dispensing unit according to the present invention for housing and dispensing the inventive pad assemblies. Dispensing unit 100 includes a housing 101 allowing multiple pad assemblies 103 to be stacked for compact storage, and an access slot 102 for allowing the user to access one pad assembly at a time. The pad assemblies as shown are individually packaged. Alternatively, pad assemblies may be packaged in bulk (e.g., 25 pads per bag/4 bags per case) for ease of storage at the user location.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the present invention.

WHAT IS CLAIMED IS:

1. A device for attachment to a compression surface of a mammography unit, said device comprising:

a pad element having at least one surface;

means for attaching said at least one surface of said pad element to said compression surface.

2. The device of claim 1 wherein said attachment means provides for releasable attachment of said at least one surface to said compression surface.

3. The device of Claim 1 wherein said means for attachment comprises an adhesive layer on said at least one surface of said pad element.

4. The device of Claim 3 wherein said adhesive layer is chosen from the following list; acrylic based adhesive, or synthetic rubber based adhesive.

5. The device of Claim 2 wherein said means for releasable attachment comprises the interface of the pad element surface and the compression surface.

6. The device of Claim 2 wherein said means for releasable attachment is the friction between the pad and the compression surface.

7. The device of Claim 2 wherein said means for releasable attachment is attached to the mammography unit on a surface other than the compression surface.

8. The device of Claim 7 wherein said means for releasable attachment is Velcro.

9. The device Claim 6 wherein said means for releasable attachment is an elastic layer.

10. The device of claim 1 wherein said pad element is radiolucent.

11. The device of claim 1 wherein said pad element is formed of a polyurethane foam.

12. The device of Claim 11 wherein said polyurethane form is an open cell foam.

13. The device of Claim 1 wherein said pad element is formed of a fully skinned closed cell foam.

14. The device of Claim 1 wherein said pad element is formed of vinyl.

15. The device of Claim 1 wherein said pad is formed of a homogeneous material.

16. A device for cushioning a compression surface of a mammograph unit, said device comprising;

a pad element having at least one surface for contacting said compression surface, wherein said pad element surface is textured such that said pad remains in contact with said compression surface due to friction between said pad element surface and said compression surface.

17. A cushioned mammography paddle comprising:

a mammography paddle having a patient contact surface;

and

a cushioning element adapted for fixed attachment to said paddle patient surface.

18. The device of Claim 17 wherein said paddle and said cushioning element are separately formed.

19. A cushioned mammography x-ray plate comprising:

an x-ray plate having a patient contact surface;

and

a cushioning element adapted for fixed attachment to said paddle patient surface.

20. The device of Claim 19 wherein said paddle and said cushioning element are separately formed.

21. A compression device for a radiological apparatus, said compression device comprising:

a compression pad wherein said compression pad has at least one cushioned surface and said compression pad and said at least one cushioned surface are substantially transparent to x-ray.

22. A device for attachment to the breast of a patient,

said device comprising:

a pad element having a first and second surface;

means for attaching said first surface of said pad element to the breast of said patient.

23. A method of performing mammography using the device of claims 1-16 wherein said method allows for the use of increased compressive force.

24. A method of performing mammography using the device of claims 1-16 wherein said device produces no significant visual artifact on the mammogram.

25. A system for use with a mammography unit comprising the devices of claims 1-16, and a dispensing unit configured to retain and dispense said devices.

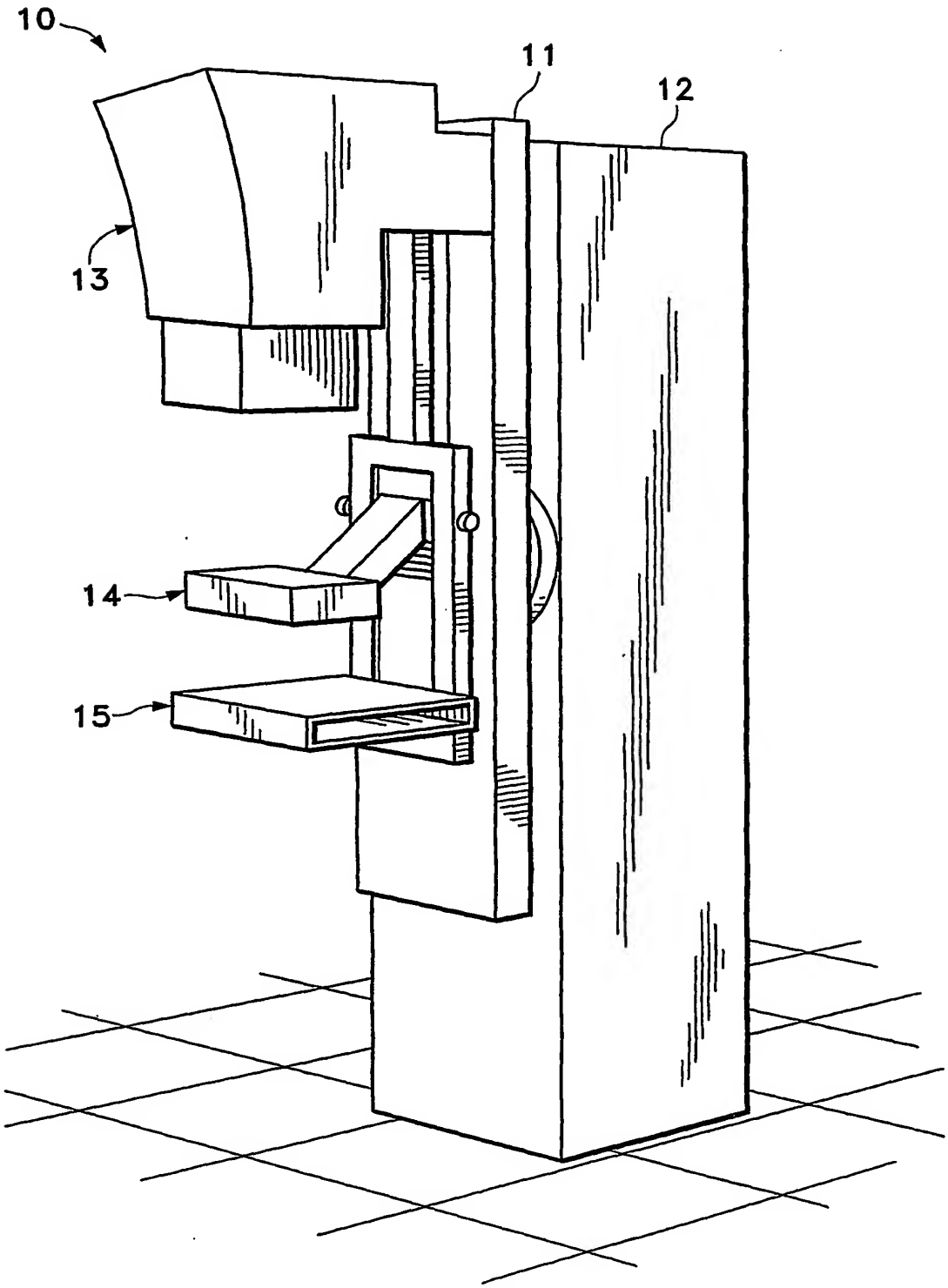


FIG. 1

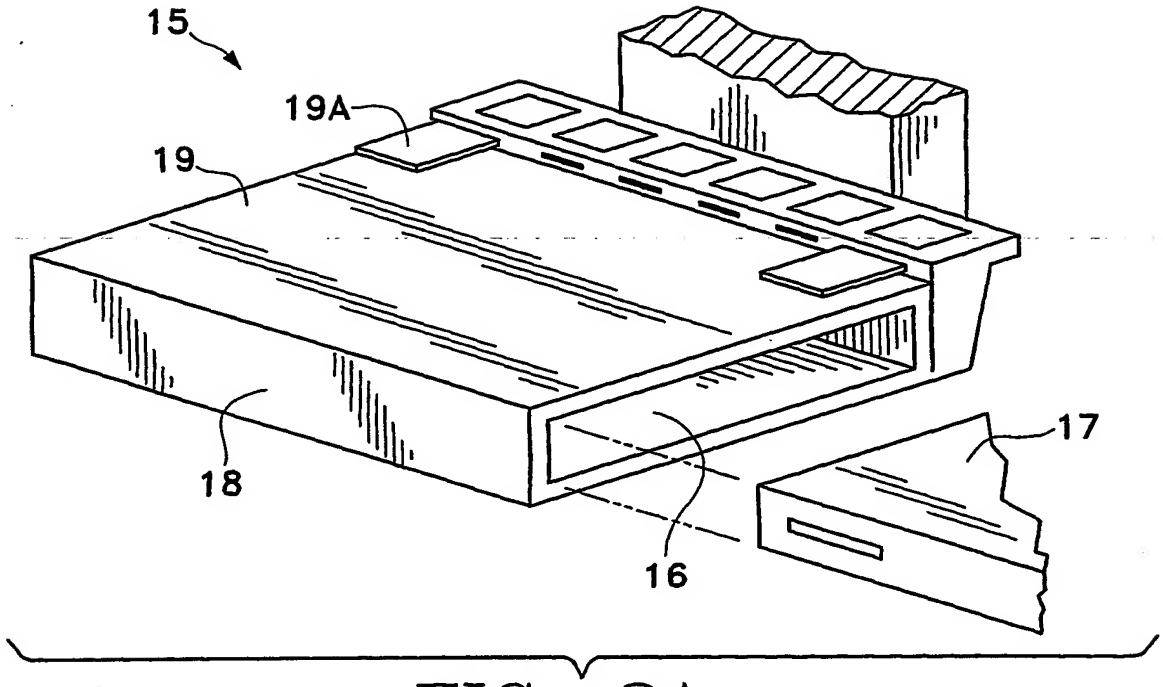
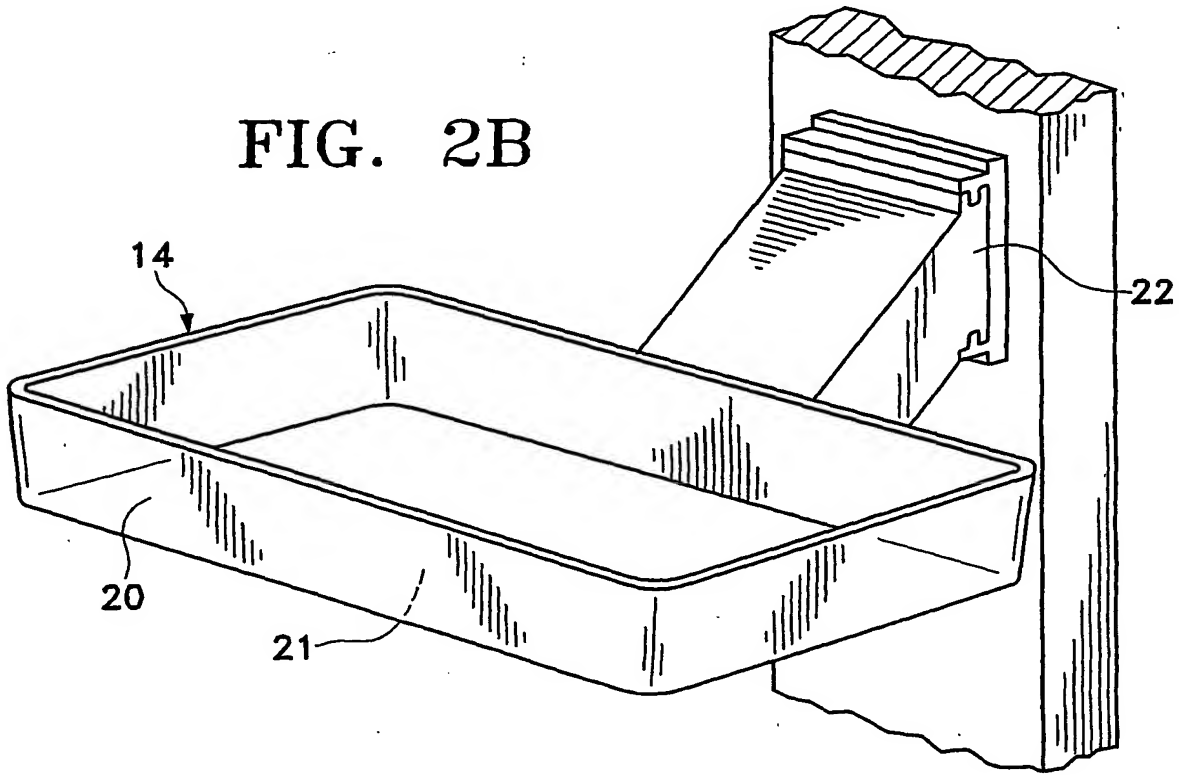


FIG. 2A

FIG. 2B



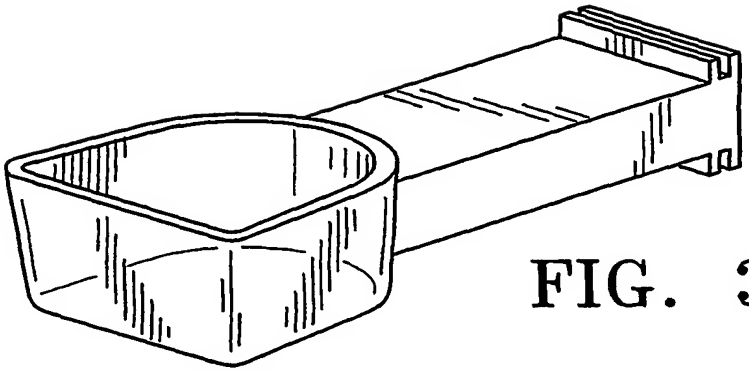


FIG. 3A

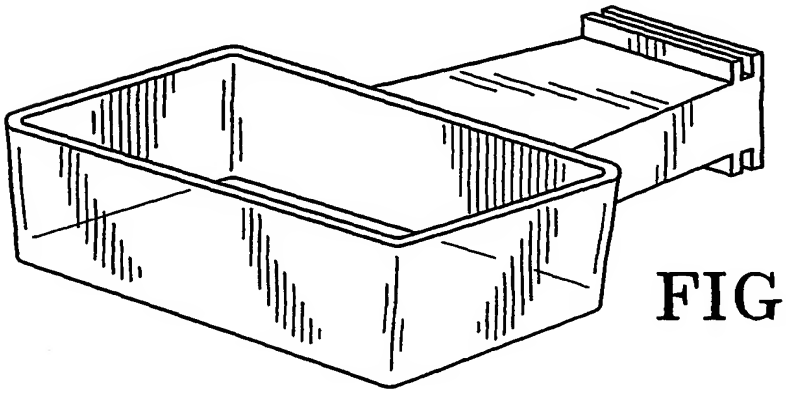


FIG. 3B

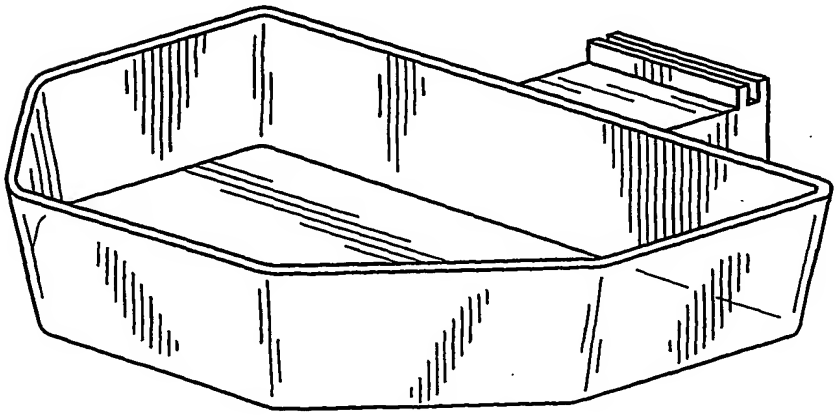


FIG. 3C

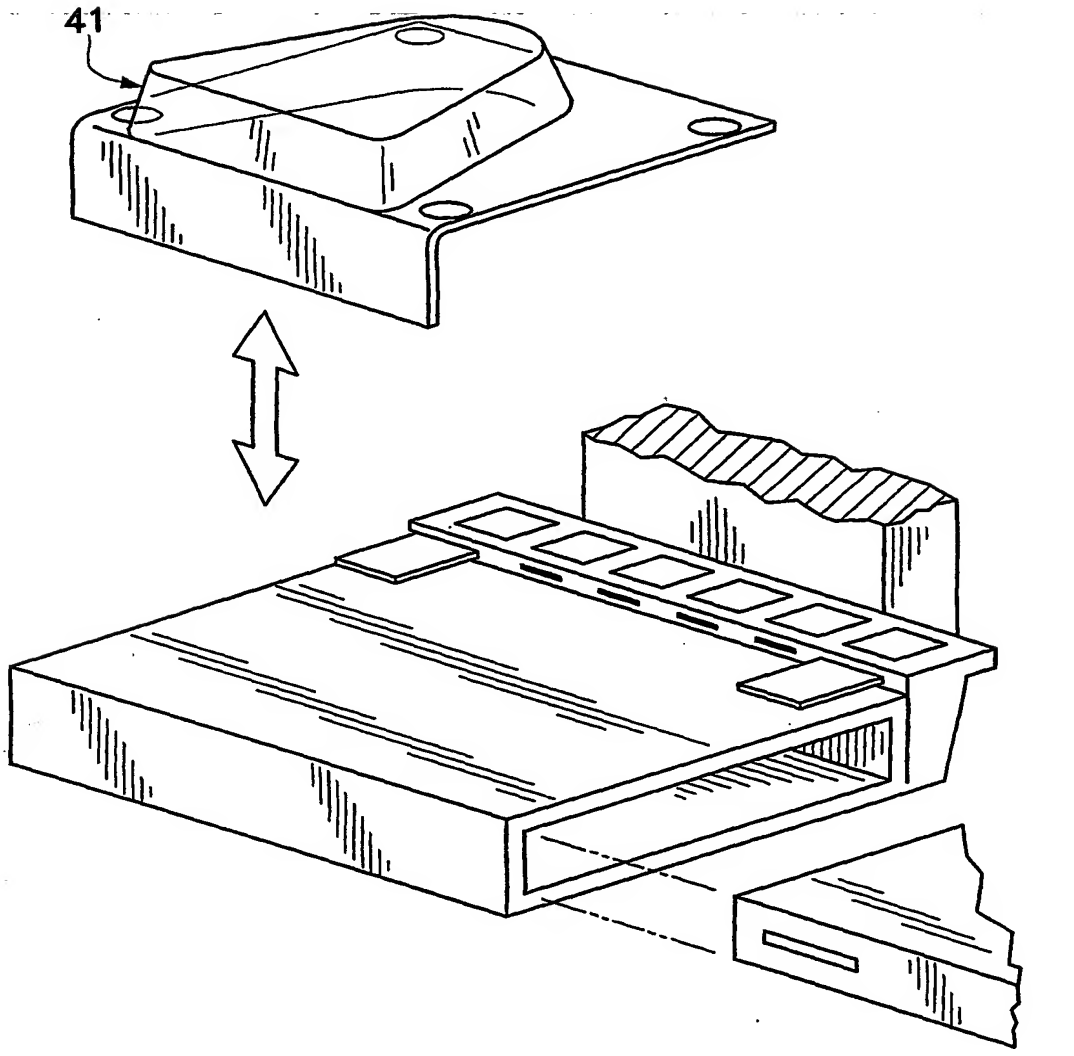


FIG. 4A

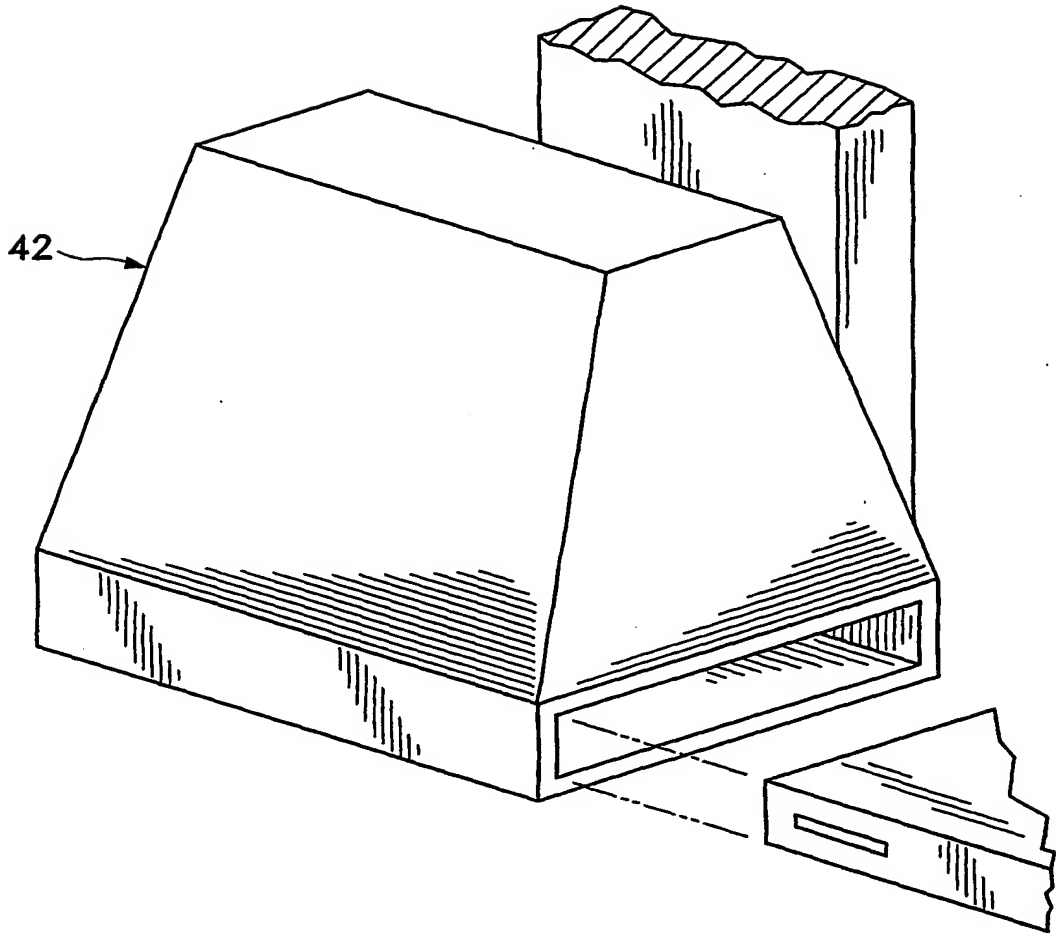


FIG. 4B

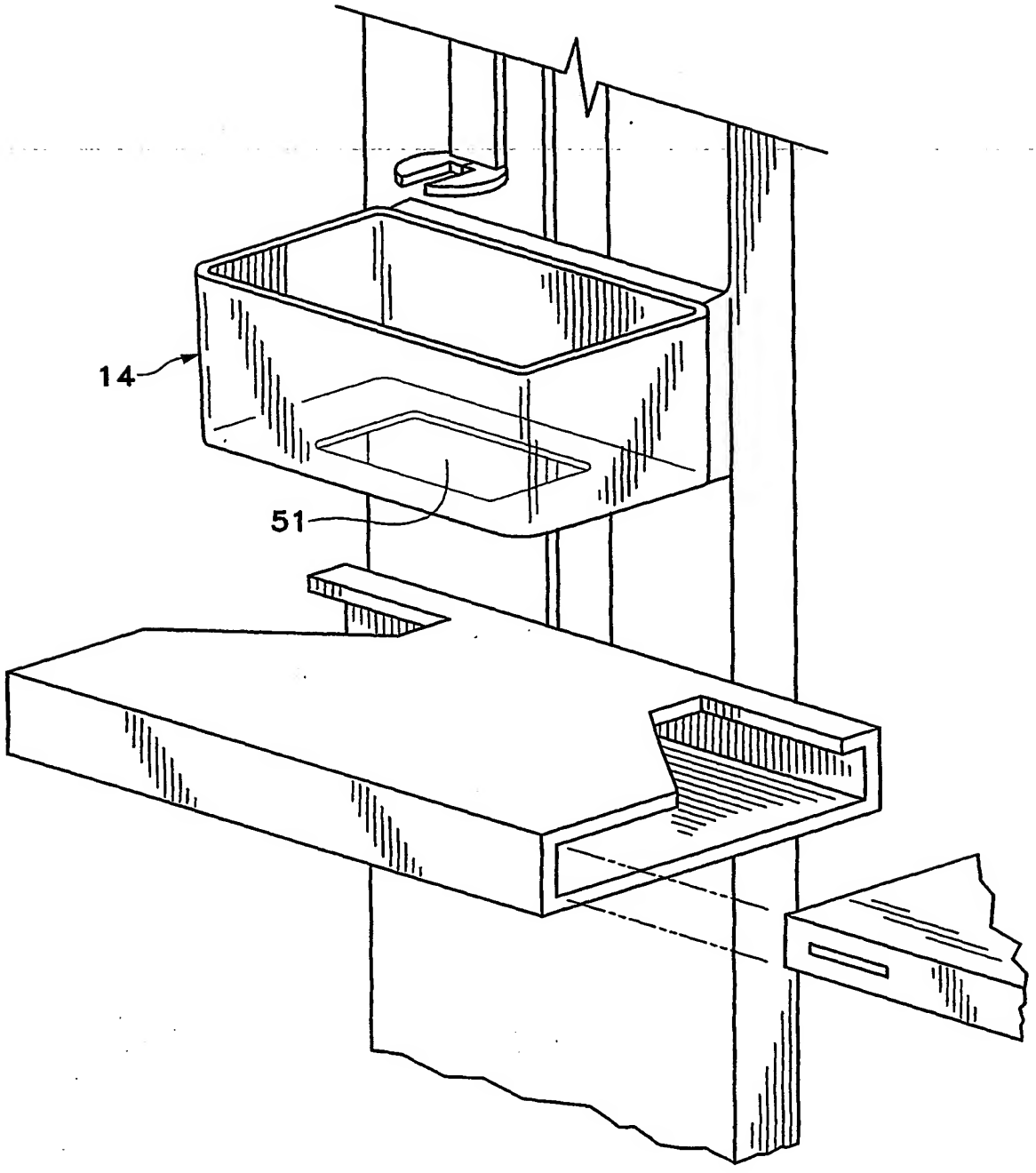


FIG. 5

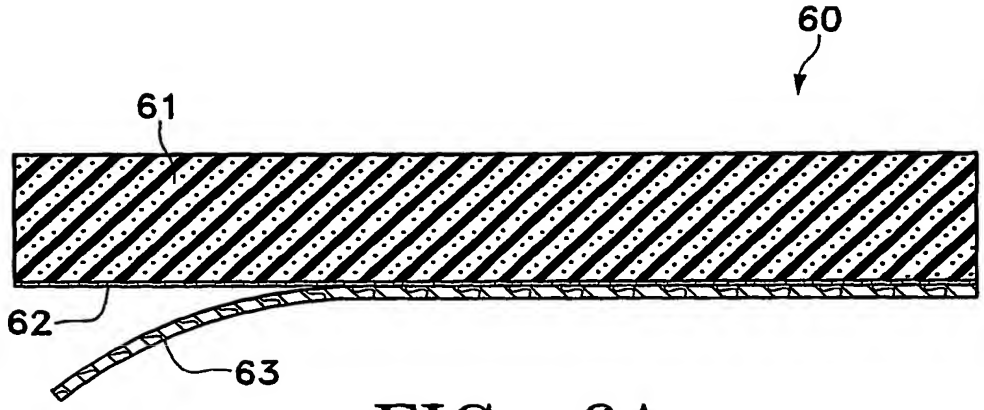


FIG. 6A

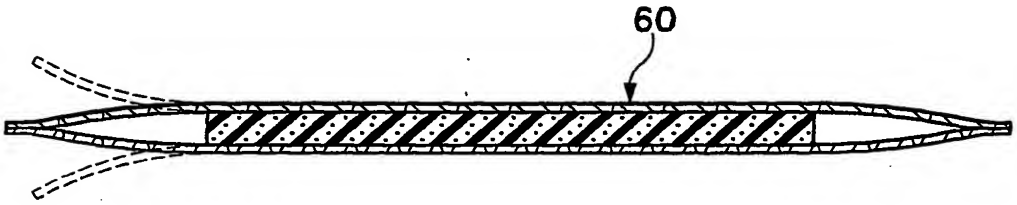


FIG. 6B

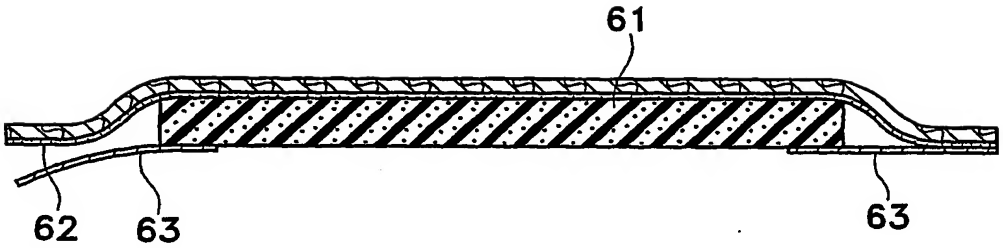


FIG. 6C

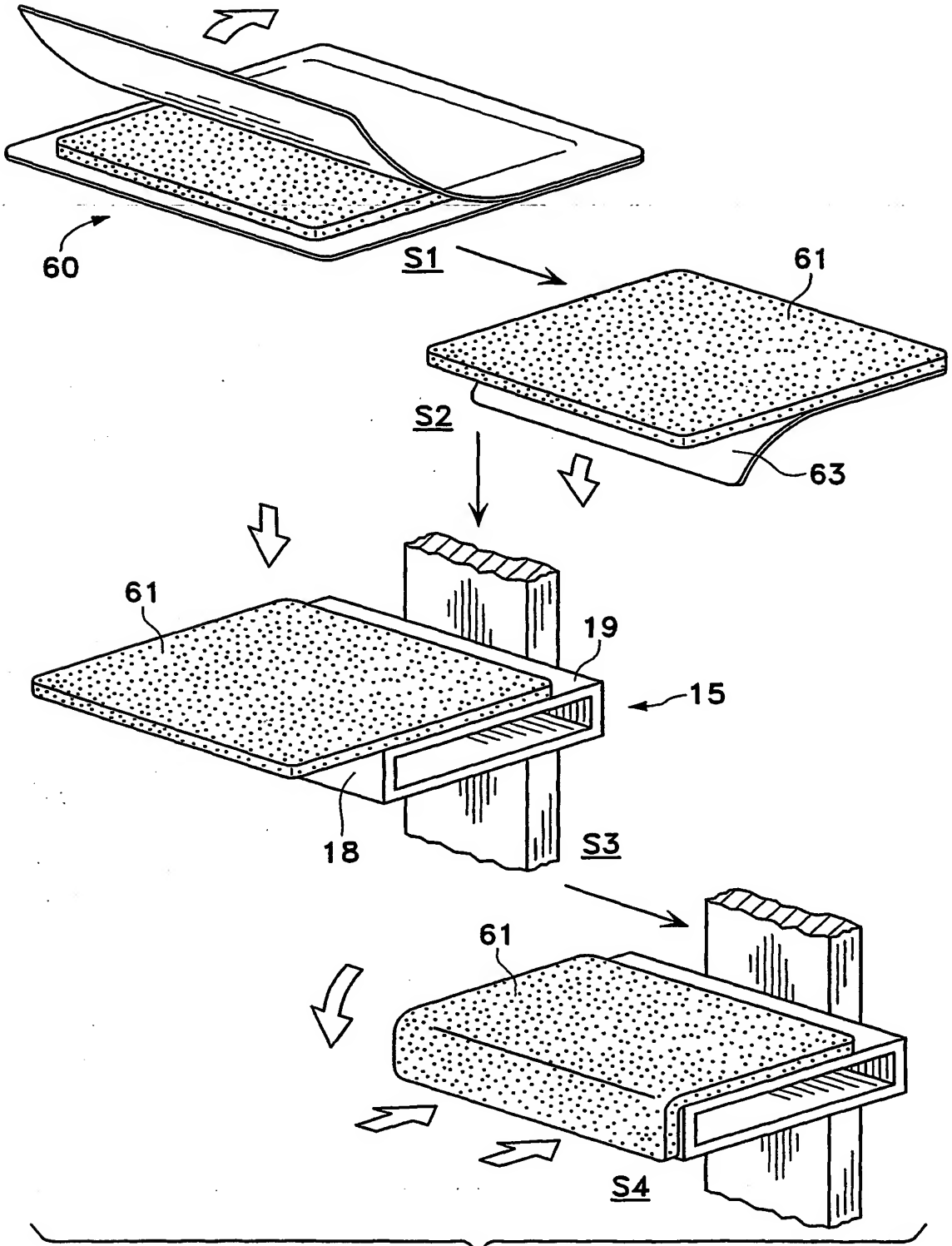


FIG. 7A

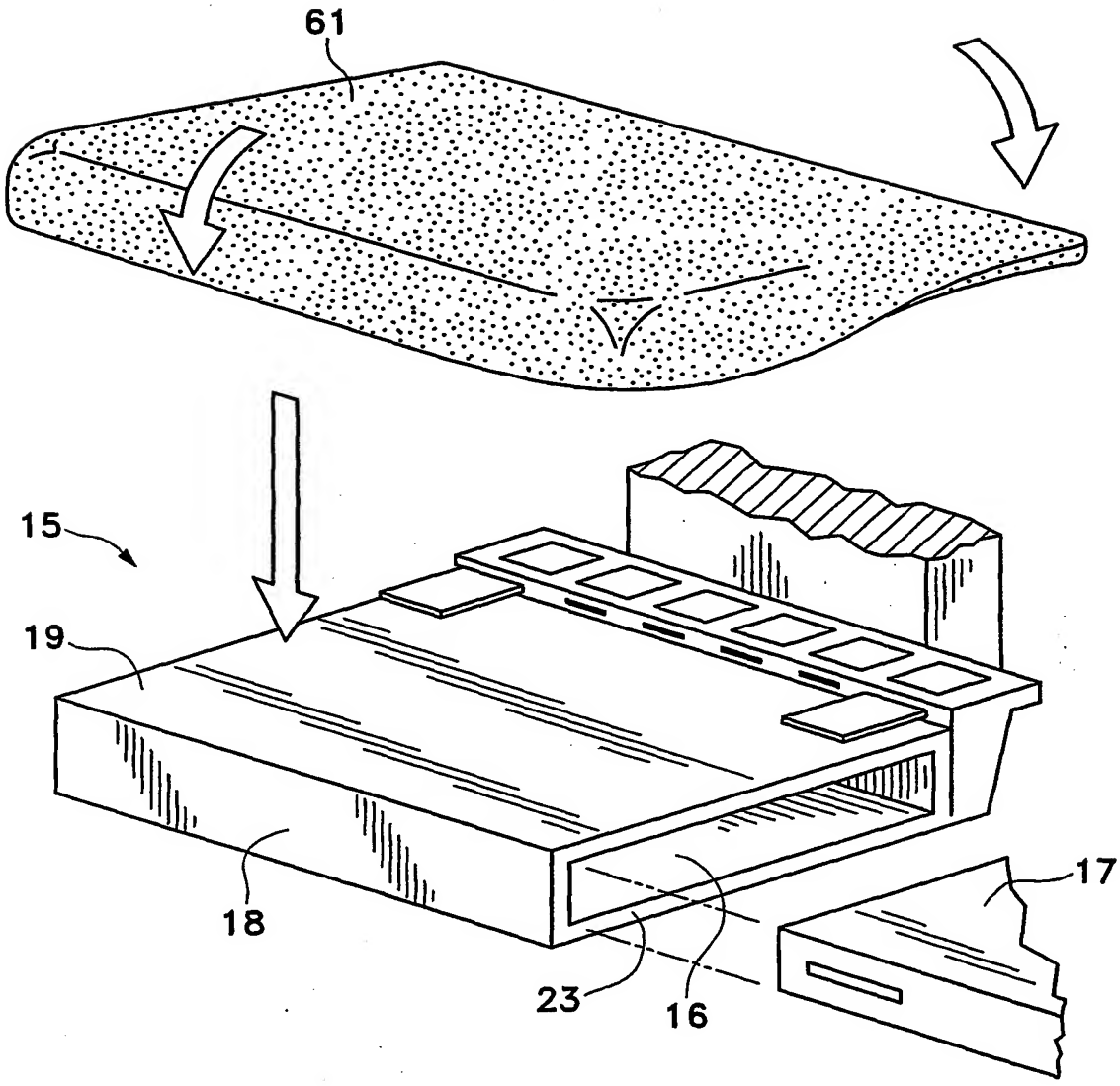


FIG. 7B

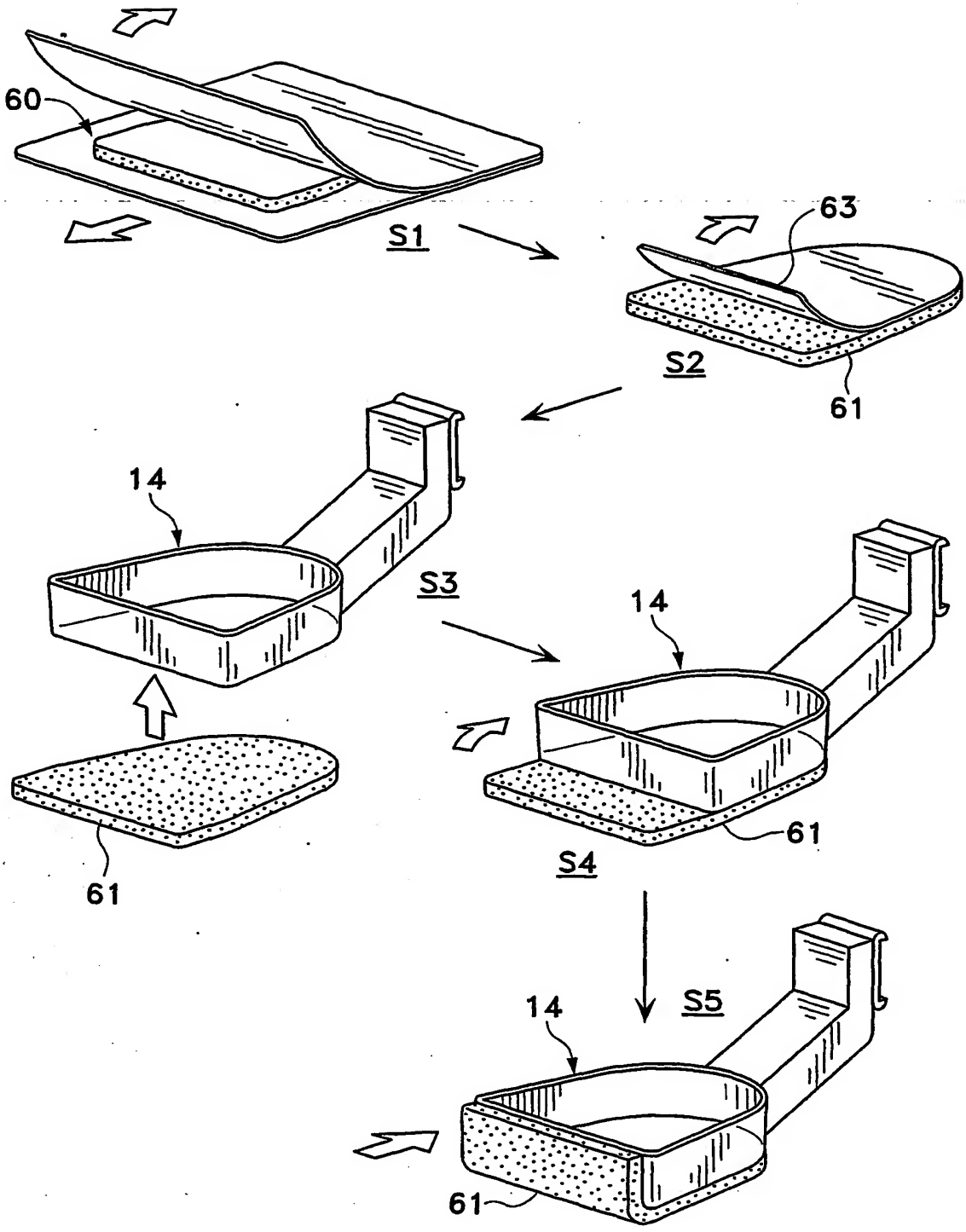


FIG. 8A

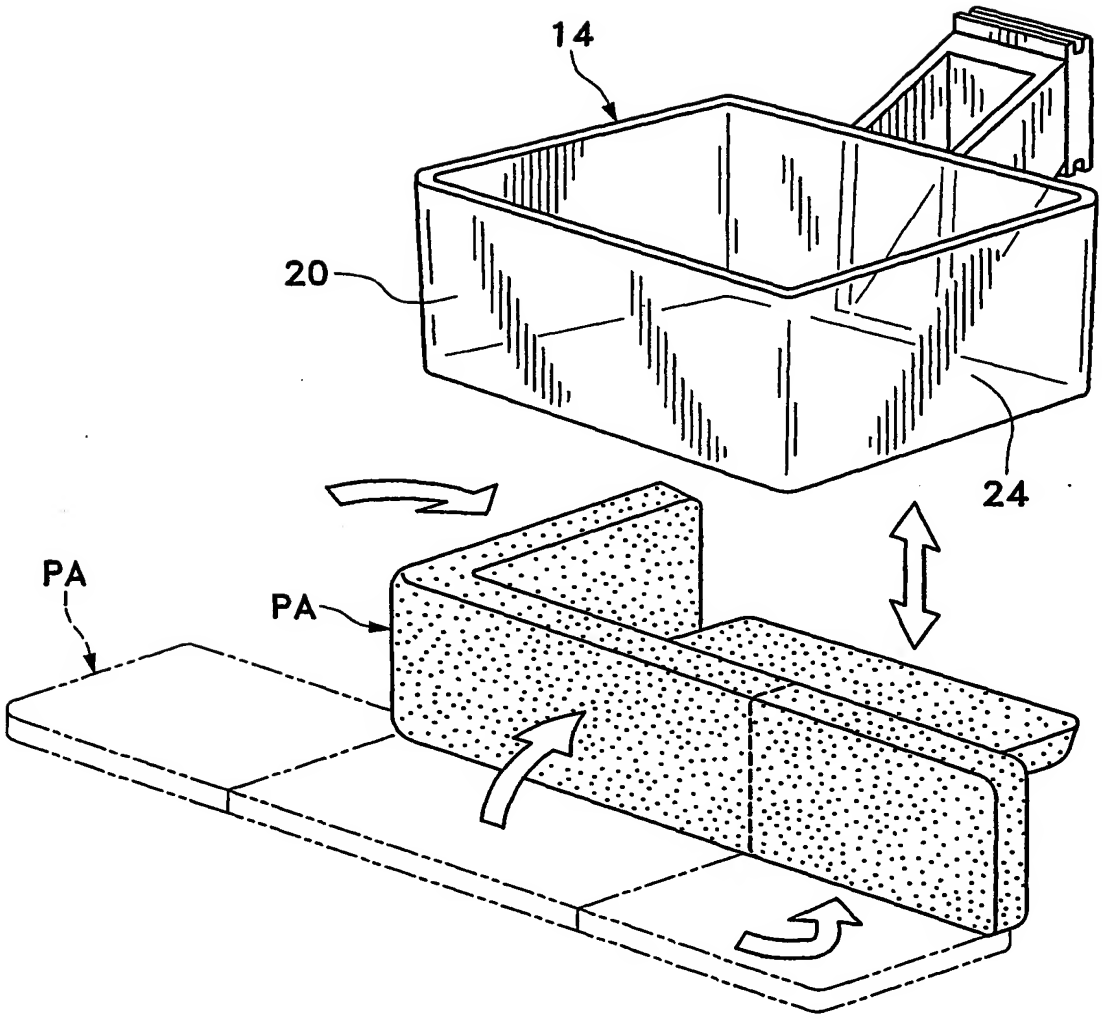


FIG. 8B

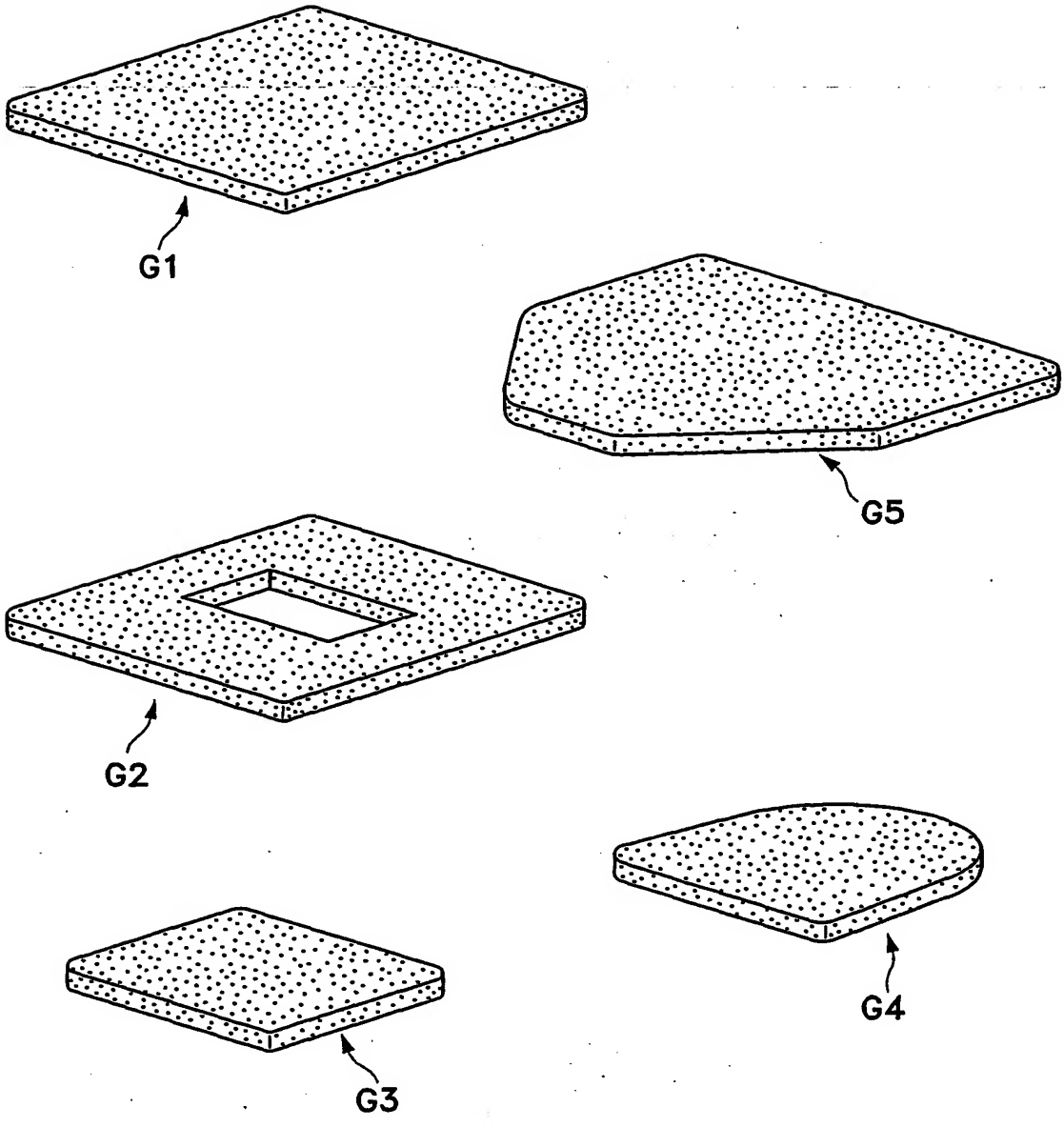


FIG. 9

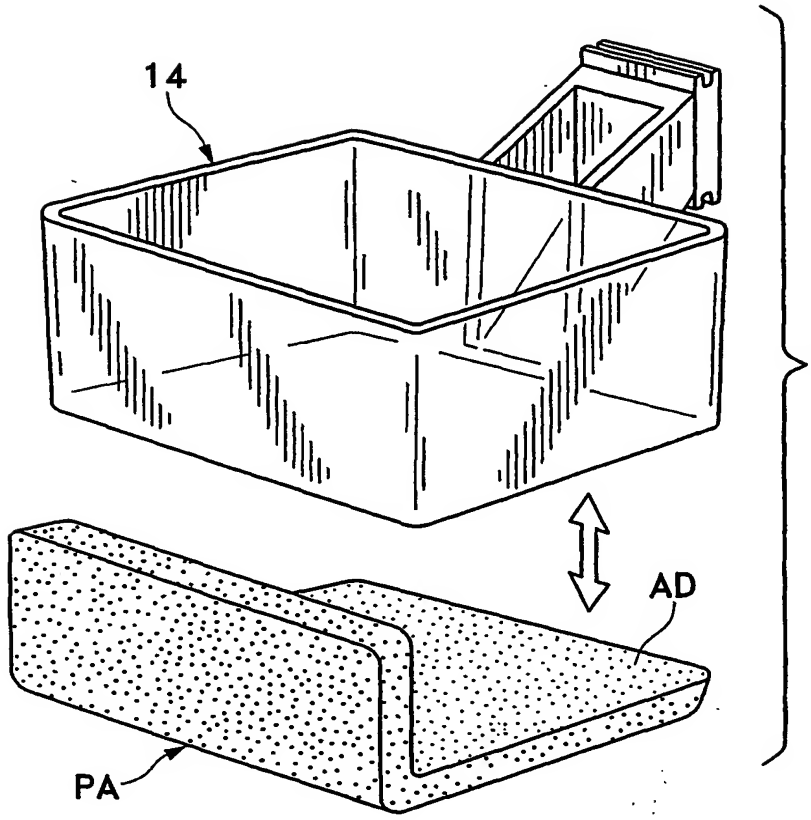


FIG. 10A

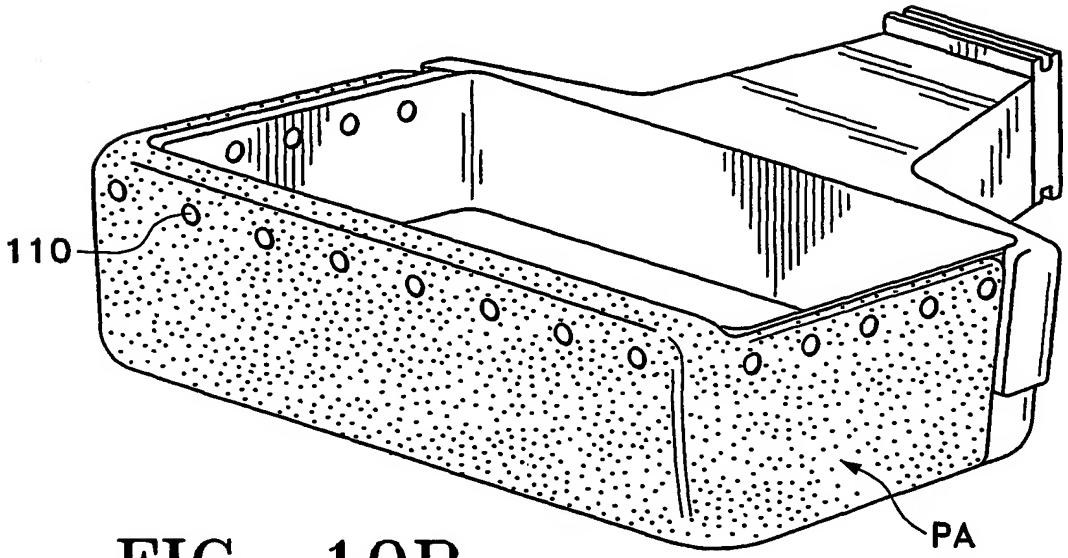


FIG. 10B

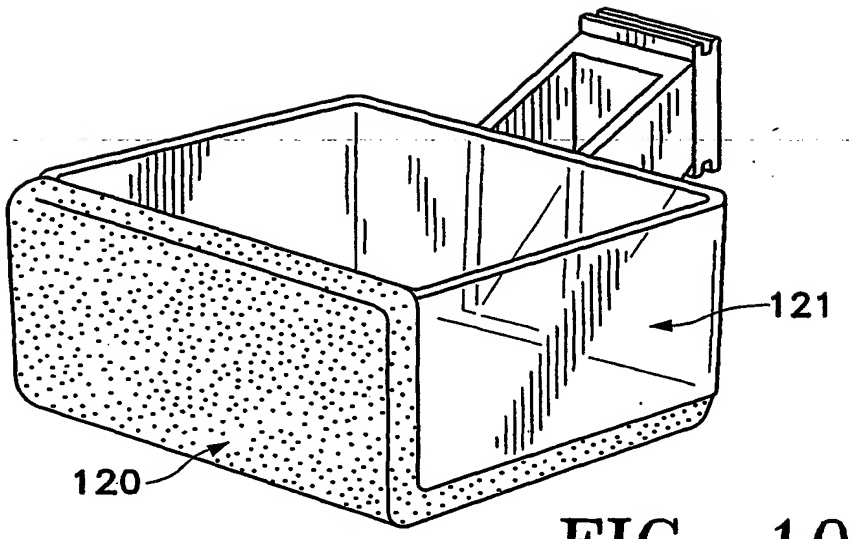
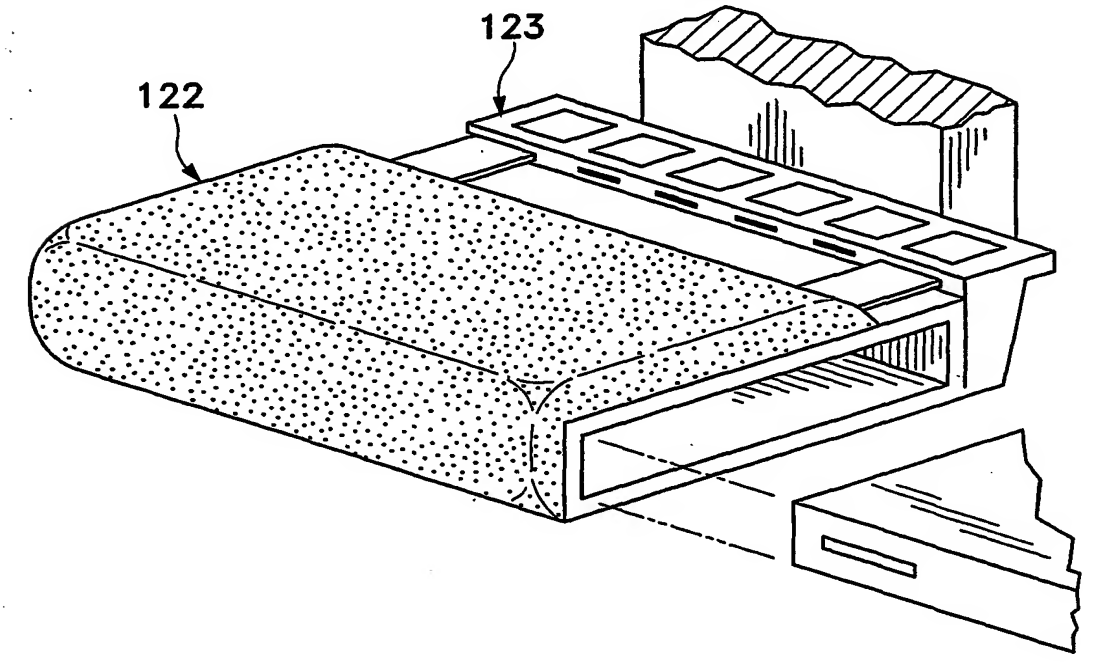


FIG. 10C

FIG. 10D



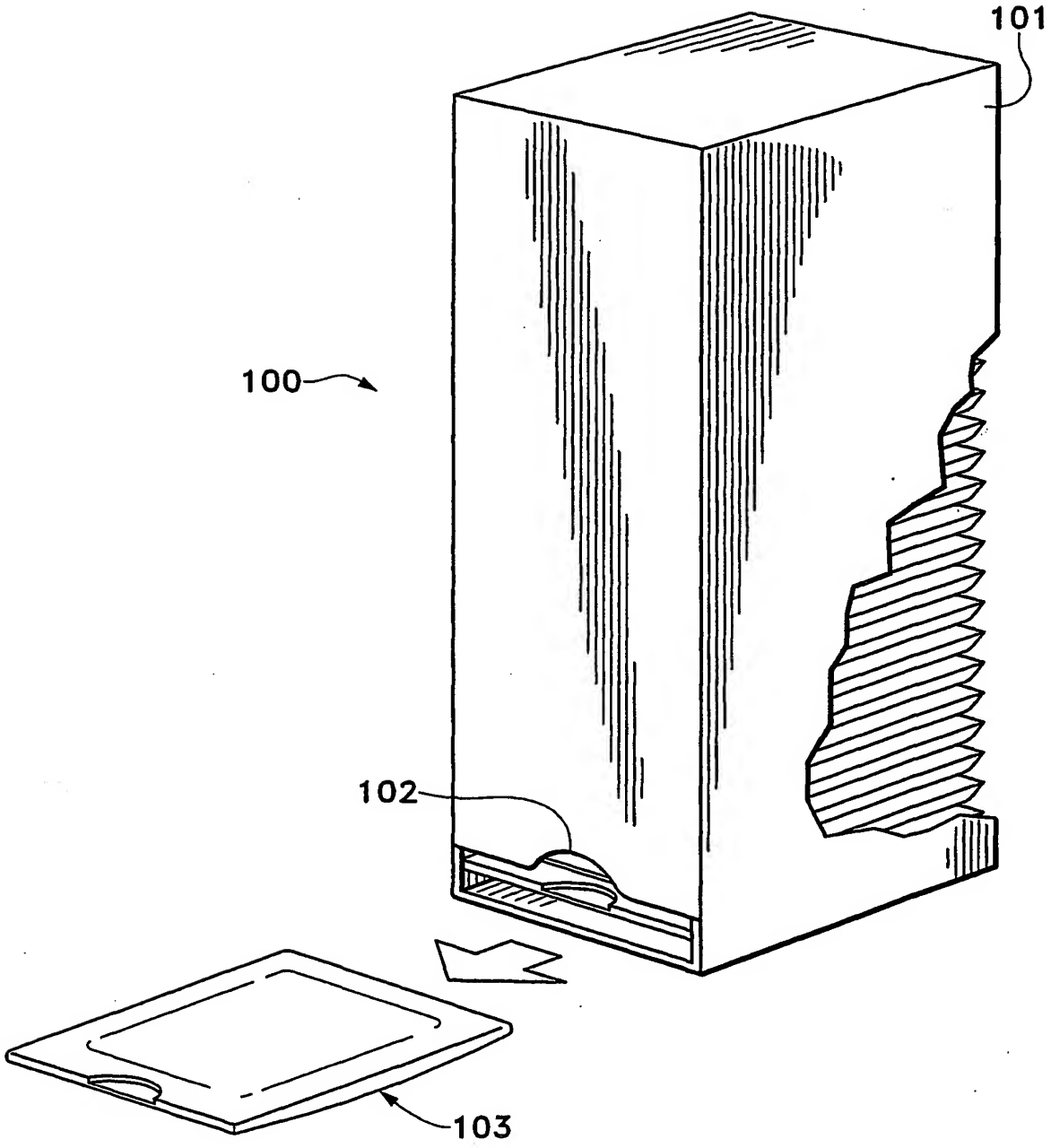


FIG. 11

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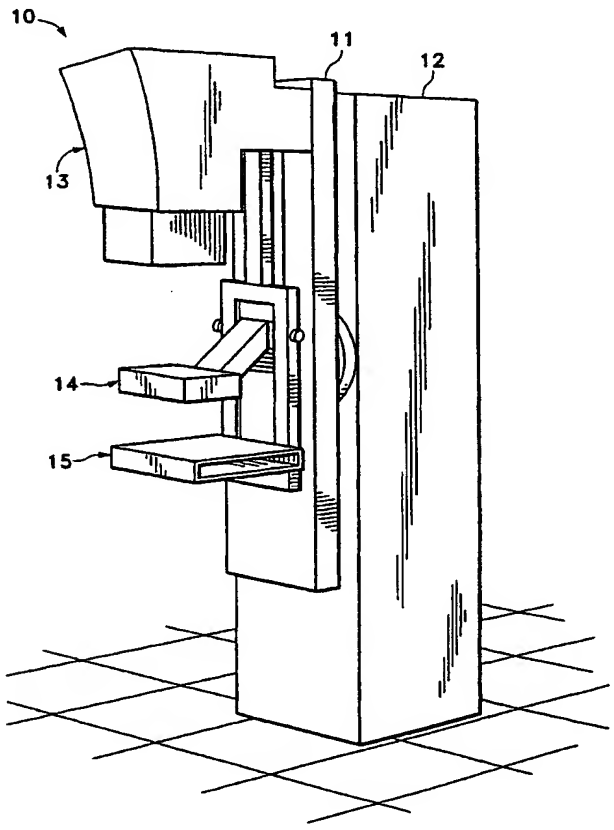
[Continued on next page]

(54) Title: DEVICE FOR CUSHIONING OF COMPRESSION SURFACES IN MAMMOGRAPH



(57) Abstract: According to the present invention, improved methods and apparatus are provided for providing cushioning and other ergonomic surfaces on devices requiring the patient or tissue to be compressed, such as radiography machines, fluoroscopy units, mammography units and the like. In particular a radiolucent pad element is provided for releasable attachment to at least one surface of a compression device to be used under x-ray, for example, during mammography. The pad element of the present invention can be disposable or constructed to be reusable and in some cases may be applied directly to the patient's breast. Furthermore, a cushioned compression paddle or x-ray plate is provided wherein said compression paddle or x-ray plate and said cushion can be separately or integrally formed.

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MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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INTERNATIONAL SEARCH REPORT

Int ional Application No
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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Date of the actual completion of the international search	Date of mailing of the international search report
4 September 2001	17/09/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Jonsson, P.O.

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